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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/067,638	04/28/98	COWSERT	ISIS-2960

HM12/0718
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EXAMINER

MARSCHER, A

ART UNIT	PAPER NUMBER
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1631

DATE MAILED: 07/18/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.
09/067,638

Applicant(s)
Cowser et al.

Examiner
Ardin Marschel

Art Unit
1631



— The MAILING DATE of this communication appears on the cover sheet with the correspondence address —

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Apr 6, 2001
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 35 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 68-82 is/are pending in the application.
- ~~As for the above, Claim(s) 1-67 have been canceled.~~ ~~is/are withdrawn from consideration.~~
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 68-82 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- a) ☐ All b) ☐ Some* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- *See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- 15) ☐ Notice of References Cited (PTO-892)
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____
- 18) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 19) ☐ Notice of Informal Patent Application (PTO-152)
- 20) ☐ Other: _____

The request, filed 4/6/01, for a Continued Prosecution Application (CPA) under 37 CFR 1.53(d) based on parent Application No. 09/240,920 is acceptable and a CPA has been established. An action on the CPA follows.

Applicants' arguments; filed 4/6/01, have been fully considered but they are not deemed to be persuasive. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

Claims 68-82 are rejected under 35 U.S.C. § 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

This rejection is reiterated and maintained the same as from the previous office action, mailed 11/6/00, and now directed to the newly submitted claims for the same reasons. Applicants argue that written basis is provided for the claimed systems by pointing to different specific descriptions in the specification as compared to their previous response, filed 8/15/00. It is revealing that the search for written support for the instantly claimed invention has not easily or successfully provided such support. Consideration of the descriptions pointed to in the

REMARKS, filed 4/6/01, revealed that none of these descriptions describe the claimed system. Applicants firstly point to the specification on page 7, line 25, through page 8, line 19. It is firstly noted that there is no mention in said section of any system therein described as being "integrated" as set forth now in claim 68, line 1. For example, the first sentence of the pointed to section on page 7, lines 25-28, the systems are automated but not disclosed as being integrated. Secondly, this sentence only indicates that they are for generation of active oligonucleotide compounds with "desired physical...properties". Then on page 7 the invention is stated as being directed to identifying "oligonucleotide-sensitive target sequences" which is reasonably interpreted as being target sequences and not oligonucleotides per se. On page 7, lines 35-36, iterative processes are cited but without any such iteration in claim 68. On page 8, lines 3-8, the *in silico* generation of a library of nucleotide sequences is described but chosen "according to defined criteria" and a target nucleic acid is provided or selected. Consideration of claim 68, lines 4-6, reveals that the target nucleic acid is cited in the computer network (apparently *in silico*) but without the virtual library being chosen according to a "defined criteria". It is noted that the system requires "particular members" in lines 2-3 to possess at least one property but the computer virtual library is not so limited.

This broadening of the *in silico* practice is clearly NEW MATTER compared to the instant disclosure as filed. It is also noted that page 8, lines 10-16, that only those oligonucleotides having particular desired properties are selected and then synthesized. Instant claim 68, lines 7-9, is not limited to the synthesis of "selected" virtual oligonucleotides. This generic synthesis is also NEW MATTER compared to the instant disclosure as filed. The assay apparatus of the last 4 lines of claim 68 performs a "real-time" polymerase chain reaction. No "real time" citation has been found as pointed to by applicants and thus also is NEW MATTER. Applicants then point to Figure 18. Consideration of Figure 18 reveals that the top row of Server, Engine, etc. lacks any indication of virtual library of oligonucleotide preparation as required in claim 68, line 4. Also, an automated synthesizer is noted at the far right but without any indication that it synthesizes oligonucleotides. Lastly, the output of said synthesizer is not in any way shown, much less sending a product of synthesis to the assay blocks of the system. It is noted that instant claim 68, lines 10-13, accepts the set of oligonucleotide from the synthesizer for assaying. There is no such transfer or acceptance of oligonucleotides shown in said Figure 18. Therefore Figure 18 fails to provide written basis for the instant claims. Applicants then point to the specification at page 61, line 33, through page 62, line 28. Consideration of

this section reveals that it is a summary of each of the components of Figure 18 but does not describe the deficiencies noted above regarding the failure of Figure 18 to provide written support for the instant claims. Applicants then point to page 14, line 28, through page 39, line 14. This large section cannot be reasonably summarized in response and has not been pointed to regarding the instantly claimed "integrated" system. Applicants are requested to succinctly point to written support for the instant claims. Applicants then separately point to descriptions of the second and third components of the claimed system. It is acknowledged that separate components are described but not as given in the instant claims as an integrated system nor generically set forth as in the instant claims. Applicants are reminded of the above specific NEW MATTER limitations of the instant claims as specifically discussed above regarding specifics of instant claim 68. Applicants then go on to point to specific limitations in claims 69-82. These are acknowledged as having support as separate entities, but not as they depend from claim 68. The several NEW MATTER aspects of claim 68 have been summarized above and provide sufficient basis for this rejection.

Claims 68-82 are rejected, as discussed below, under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 68, last 2 lines, an assay is indicated as being a "polymerase chain reaction". This causes the claims to be vague and indefinite in that such a reaction only amplifies the amount of nucleic acid in a sample and is not an assay. Clarification of the claims as to what assay is meant by PCR via clearer claim wording is requested.

No claim is allowed.

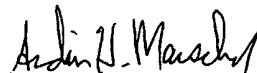
Papers for this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993) (See 37 CFR § 1.6(d)). The CM1 Fax Center number is either (703)308-4242 or (703)305-3014.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ardin Marschel, Ph.D., whose telephone number is (703)308-3894. The examiner can normally be reached on Monday-Friday from 8 A.M. to 4 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward, Ph.D., can be reached on (703)308-4028.

Any inquiry of a general nature or relating to the status of this application should be directed to Patent Analyst, Tina Plunkett, whose telephone number is (703)305-3524 or to the Technical Center receptionist whose telephone number is (703)308-0196.

June 29, 2001


ARDIN H. MARSCHEL
PRIMARY EXAMINER